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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/713,749	11/14/2000	Daniel M. LaFontaine	259/012	6224

7590

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EXAMINER

FARAH, AHMED M

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 08/19/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/713,749

Applicant(s)
LaFontaine et al.

Examiner
Ahmed M. Farah

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3739



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 14, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-70, 72-79, and 81-84 is/are pending in the application.
- 4a) Of the above, claim(s) 64-69 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 70 and 72-78 is/are allowed.
- 6) ☒ Claim(s) 79 and 81-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 and 1 6) ☐ Other: _____

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DETAILED ACTION

Specification

1. The abstract of the disclosure is objected to because it exceeds 150 word.

Correction is required. See MPEP § 608.01(b).

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

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Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 79 and 81 are rejected under 35 U.S.C. 102(b) as being anticipated by Qian U.S. Patent No. 5,047,028.

Qian discloses apparatus and method for creating thrombosis of vessel under the surface of a body cavity, the method comprising the steps of:

inserting the distal portion of tubular member **10** into the patient's body, the distal portion comprising an expandable member (balloon **12**) in a collapsed condition (see the abstract; Col. 1, lines 18-23; Col. 2, lines 8-10; and claim 1), and an electrode (conducting wire **16** connected to an external electrode **20**) within an interior space of the expandable member;

positioning the distal portion of the tubular member proximate a target site (Col. 2, lines 10-11);

directing electrolyte fluid through the lumen of the tubular member and into the interior space of the expandable member (Col. 2, lines 11-15); and

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energizing the electrode with electrical energy, thereby transferring electrical energy from the electrode through the expandable member via the electrolyte fluid to ablate the target site (see claim 9),

wherein the expandable member comprises a plurality of perforations (semi-permeable wall) through which the electrolyte fluid flows to the target site (Col. 2, lines 15-19).

In this Office Action, the word **ablation** is defined as 'the surgical excision or amputation of body part or tissue by cutting, heating/coagulating, and/or removing body tissue using mechanical (i.e., ultrasound), electrical and/or optical energy. This interpretation is in line with the common use of the word 'ablation' in the relevant art.

Furthermore, the word **thrombosis** is defined as "the formation, presence, or development of a thrombus (A fibrinous clot formed in a blood vessel¹); the word **clot** is defined as "a thick, viscous, or coagulated mass or lump, as of blood;¹" and the word **coagulate** is defined as 'the phase transformation of (a liquid or sol, for example) into a soft, semisolid or solid mass, which results from heating or cooling the mass (a biological tissue in this case).'

Therefore, since thrombosis results from a coagulated/ablated tissue, Qian teaches a method for ablating body tissue as presently claimed.

As to claim 81, the expandable member (balloon 12) of Qian is expanded as the electrolytic fluid is directed into its interior space (Col. 2, lines 13-15).

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5. Claims 82-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Rexroth et al. U.S. Patent No. 4,943,290.

Rexroth et al. disclose electrosurgical apparatus for ablating (cutting or coagulating) body tissue (Col. 7, lines 53-56), the apparatus comprising:

a source of RF energy (power source **12**);

a catheter having a proximal portion attachable to a source of fluid **14** (conductive/non-conductive fluid), a distal portion sized for insertion into a patient's body, and a lumen **18** for delivering fluid from the proximal portion to the distal portion (see **Fig. 1**);

a porous member **72** disposed at the distal portion of the catheter, the porous member defining interior region in communication with lumen **18**, the interior region capable for receiving fluid (conductive/non-conductive fluid) delivered from the proximal end; and

an electrode **60** disposed in the interior region of lumen **18** and coupled to the source of the RF energy.

As to claim 83, the most distal end **62** of the electrode extends from the distal portion of the catheter.

As to claim 84, the porous member **72** has a substantial planar distal end as presently claimed.

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Allowable Subject Matter

6. Claims 70, 72-78 are allowed. The prior art of record fails to teach or suggest a device for ablating body tissue using an RF energy as presently claimed, the device comprising an expandable member disposed on the distal portion of the catheter and comprising a substantially planar distal end, the expandable member defining an interior region in communication with the lumen, whereby RF energy may be transferred from the electrode to selected tissue areas in a patient's body via electrolyte fluid delivered through the lumen and into the interior region of the expandable member.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See the following references:

U.S. Patent No. 4,979,948 to Geddes et al. teaches method and apparatus for thermally destroying a layer of an organ. Their apparatus comprises a catheter **100**, which includes an elongated member **103** with a current-emitting electrode 104 positioned on the distal end of the catheter for emitting RF energy to the organ.

U.S. Patent No. 5,460,628 to Neuwirth et al. discloses a method and apparatus for ablating body tissue, the apparatus comprising an elongated catheter body 1 having a proximal portion attachable to a fluid source (conductive and/or non-conductive), a distal end sized for insertion into a patient's body, and lumen for delivering fluid from


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the proximal portion to the distal portion; an expandable member **5** disposed on the distal end of the catheter, the expandable member comprising a substantially planer distal end; and an electrode **44** for heating a fluid within the expandable member. Their system is not designed to transfer RF energy from the electrode to selected tissue in a patient's body via electrolyte fluid (conductive fluid) delivered through the catheter and into the interior region of the expandable member.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. Farah whose telephone number is (703) 305-5787. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak, can be reached on (703) 308-0994. The official fax number for the group is (703) 872-9302; the fax number for After Final is (703) 872-9303; and the Examiner's Desk-top fax is (703) 746-3368.

A. M. Farah

Patent Examiner (Art Unit 3739)



August 11, 2003

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